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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,226

05/06/2005

Carsten Horn

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7590

03/19/2009

Gail Poulos

USDA ARS Office of Technology Transfer

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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

03/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,226	Applicant(s) HORN ET AL.	
	Examiner Valarie Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2008 and 14 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 23, 25-34 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-22, 24, 35-46 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's reply dated 12/05/2008 is noted. Applicant's amendments to the claims dated 12/05/2008 and Remarks dated 07/14/2008 are considered.

Claims 1-48 are pending. Claims 1-10,23,25-34 and 47 are withdrawn. Claims 11-22,24,35-46 and 48 are under examination in the instant office action.

Claims 35-46 and 48 are examined only to the extent that they read on the elected invention, specifically methods involving invertebrates. Thus, the examined subject matter of claims 35-46 and 48 is the same as that of claims 11-22 and 24. Claims should be limited to the elected subject matter prior to allowance of the elected invention.

Priority

The certified copy of the DE 10251918.8 application was received 07/14/2008.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-22,24, 35-46 and 48 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of integrating a heritable integration of a transgene into the genome of a somatic or germ line cell of an invertebrate organism said method comprising, i) integrating a first acceptor DNA cassette into said genome by transposase-mediated integration of a first vector wherein the first vector comprises said first acceptor DNA cassette flanked on each end by first and second transposon half sides and wherein said first DNA cassette comprises heterospecific site-specific recombinase target sites flanking each end of a first marker gene and ii) exchanging said first

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acceptor DNA cassette for a second donor DNA cassette by recombinase-mediated site-specific recombination using a second vector comprising a second DNA cassette comprising heterospecific site-specific recombinase target sites flanking each end of an internal transposon half side followed by a second marker gene *wherein upon site-specific recombinase mediated recombination, said internal transposon half side and a first flanking half side form a pair of excisable transposon halvesides*, does not reasonably provide enablement for any second donor vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's amendments and remarks are noted but are not fully persuasive. Applicant's amendments do address the rejection in part. However, certain aspects of the structures claimed remain broad. The claim does not require that the recombinase target sites of the donor cassette be homospecific to those of the acceptor sites. Thus, the claims encompass having four different recombinase targets that do not recombine with one another. The claims do not require the recombinase target sites flank the internal transposon half side. The claims also fail to require that the internal transposon half side be such that excision with one of the flanking Tn half-sides can occur. Finally, as noted in the previous office action dated 04/11/2008, the method, as claimed, fails to 'target' an integration into the genome because the acceptor DNA is randomly integrated and the claims lack a step of identifying a selecting an integration site as a desired target. While the nature of the marker genes or additional DNA is not essential to the invention, the orientation and identity of the Tn and recombinase target sites must be clarified and specified. As well, the placement of various elements either between flanking Tn half sides or recombinase targets should be clearly recited. Method steps essential to the invention must also be included as set forth in the rejection dated 04/11/2008.

Claim Rejections - 35 USC § 112-2nd paragraph

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 45 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 45 remain unclear because, as amended, it is not clear if the operable promoter of line 4 is the same as that now recited in line 2.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio/
Primary Examiner, Art Unit 1632

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